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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO.
09 780,576	02/09/2001	Oliver Civelli	P-UC 4530	1610

23601 7890 04/15/2003  
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EXAMINER
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LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/15/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/780,576	CIVELLI ET AL.
	Examiner Ruixiang Li	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 24 January 2003.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3-7,9-12,14-17 and 19-45 is/are pending in the application.

4a) Of the above claim(s) 21-33 is/are withdrawn from consideration.

5) Claim(s) 3,9,14 and 19 is/are allowed.

6) Claim(s) 1, 4-7, 10-12, 15-17, 20, and 34-45 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 09 February 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### **I. Status of Application, Amendments, and/or Claims**

The amendment filed in Paper No. 16 on January 24, 2003 has been entered in full. Claims 2, 8, 13, and 18 have been canceled. Claims 1, 3, 7, 9, 12, 14, 17, 19 have been amended. Claims 34-45 have been added. Claims 1, 3-7, 9-12, 14-17, 19, 20, and 34-45 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **II. Drawings**

The proposed drawing correction for Figs 2-5 is approved by the Examiner.

### **III. Information Disclosure Statement**

The references listed in the corrected FORM PTO 1449 (Paper No. 17) have been fully considered by the Examiner.

### **IV. Withdrawn Objections and/or Rejections**

The objection of claims 3, 9, 14, and 19, as set forth at page 7 of the previous Office Action (Paper No. 14, September 24, 2002), has been withdrawn in view of applicants' amendment to the claims.

The rejection of claims 1, 4-7, 10-12, 15-17, and 20 under 35 U.S.C. 102 (a), as set forth at page 6 of the previous Office Action (Paper No. 14, September 24, 2002), has been withdrawn in view of applicants' amendment to the claims and arguments.

The rejection of claims 2, 8, 13, and 18 under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph, as set forth at page 3 of the previous Office Action (Paper No. 14, September 24, 2002), has been withdrawn in view of applicants' cancellation of the claims.

#### **V. Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Scope Enablement)**

Claims 1, 4-7, 10-12, 15-17, 20, 34-45 are rejected under 35 U.S.C. 112, 1<sup>st</sup> paragraph. The basis for the rejection is set forth at page 6 of the previous Office Action (Paper No. 14, September 24, 2002).

Applicants argue that the specification provides guidance that would have allowed one skilled in the art to obtain a variety of minor modifications of SEQ ID NO: 2 that transduce a G-protein coupled signal in response to ADP-glucose without undue experimentation (2<sup>nd</sup> paragraph of page 10; page 12). Applicants further submit Exhibit A-F as evidence that one skilled in the art would be able to obtain a naturally occurring modification of SEQ ID NO: 2 (last paragraph of page 10 to 11; 2<sup>nd</sup> paragraph of page 12).

This has been fully considered, but is not deemed to be persuasive for the following reasons. First, while providing some general guidance on modifying amino acid residues of SEQ ID NO: 2, such a guidance is not sufficient to guide an artisan to make an ADP-glucose receptor polypeptide which is at least 85%, 95%, or 99%

identical to SEQ ID NO: 2 while retaining its function. This is because the instant disclosure fails to disclose the binding domains of the ADP-glucose receptor of SEQ ID NO: 2 and the residues that are critical for its activity. Secondly, the exhibits provided by the applicants do not support applicants' argument because none of the amino acid sequences is a functional ADP-glucose receptor. For example, Exhibit A is a P2Y12 platelet ADP receptor, not an ADP-glucose receptor.

Applicants argue that the specification describes library screening with a detectable ADP-glucose receptor nucleic acid molecule or antibody to identify an ADP-glucose receptor nucleic acid molecule (2<sup>nd</sup> paragraph of page 11) and that specification also teaches that an ADP-glucose receptor polypeptide can be tested for functional activity using a variety of assays (1<sup>st</sup> paragraph of 1 of page 13). This has been fully considered, but is not deemed to be persuasive because there are no working examples and specific and sufficient guidance regarding how to make a functional ADP-glucose receptor variant which is at least 85%, 95%, or 99% identical to SEQ ID NO: 2. It would take undue experimentation to make a functional ADP-glucose receptor variant. The prior art indicates that, at the time when the instant application was filed, there were no functional ADP-glucose receptors which share at least 85%, 95%, or 99% amino acid identity with SEQ ID NO:2. Even after filing date, there is still no definitive evidence indicating that such a functional ADP-glucose receptor variant has discovered.

Applicants argue that the portions of SEQ ID NO: 2 that are critical for binding or functional activity of the ADP-glucose receptor is unimportant with respect naturally occurring modifications of SEQ ID NO: 2 (bottom of page 13). The Examiner disagrees.

Functional homologues or variants have certain conserved amino acid residues and the critical residues for binding or functional activity of the ADP-glucose receptor are most likely to be conserved. Knowing this information can certainly help determine whether an amino acid sequence is a homologue with the same activity.

Applicants further argue that the specification teaches how to make non-naturally occurring modifications of SEQ ID NO: 2, i.e., once orthologs of SEQ ID NO: 2 from other species are identified, the sequence can be compared with SEQ ID NO:2 to determine which portions of SEQ ID NO: 2 can be modified while retaining functional activity of SEQ ID NO: 2 (top of page 14). This has been fully considered, but is not deemed to be persuasive because it would take undue experimentation to make such non-naturally occurring modifications of SEQ ID NO: 2 in order to practice the method of the present invention. The invention is required to be enabled under 35 U.S.C. § 112, 1<sup>st</sup> paragraph at the time when the application is filed, and in its currently available form. To perform such a series of experiments as applicants have argued is clearly undue.

Accordingly, the disclosure fails to enable one skilled in the art to make functional homologues or variants of SEQ ID NO:2 and to use the claimed method without undue experimentation.

## **VI. Claim Rejections Under 35 U. S. C. § 112, 2<sup>nd</sup> Paragraph**

(i) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 1, 4-7, 10-12, 15-17 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because they recite the term "a minor modification of SEQ ID NO: 2", which refers to one or more additions, deletions, or substitutions compared with SEQ ID NO: 2. It is unclear what are the metes and bounds of the term.

## **VII. Conclusion**

Claims 3, 9, 14, and 19 are allowed.

## **THIS ACTION IS MADE FINAL.**

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

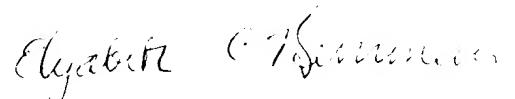
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Ruixiang Li  
Examiner  
April 10, 2003

ELIZABETH KEMMERER  
PRIMARY EXAMINER